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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,680	09/19/2001	Michael J. O'Neil	101896-0031	1266
21125	7590	09/23/2008	EXAMINER	
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				HOFFMAN, MARY C
ART UNIT		PAPER NUMBER		
3733				
			NOTIFICATION DATE	DELIVERY MODE
			09/23/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/955,680	O'NEIL, MICHAEL J.	
	<b>Examiner</b>	<b>Art Unit</b>	
	MARY HOFFMAN	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07/01/2008.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 7-11 and 13-26 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 20-26 is/are allowed.  
 6) Claim(s) 7-11, 13-15, 17 and 19 is/are rejected.  
 7) Claim(s) 16 and 18 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 19 September 2001 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Allowable Subject Matter***

Claims 16 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 20-26 are allowed.

The indicated allowability of claims 9-11, 14-15, 17 and 19 is withdrawn in view of the newly discovered reference(s) to Zdeblick et al. (6,595,995), Pasquet et al. (U.S. 6,716,245), and Lin (U.S. Patent No. 6,569,168). Rejections based on the newly cited reference(s) follow.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7-8 and 13, 17 and 19 rejected under 35 U.S.C. 102(e) as being anticipated by Zdeblick et al. (U.S. 6,595,995).

Zdeblick et al. disclose a prosthesis alignment verification system, comprising an alignment verification device (see FIG. 21) including a spacer element (ref. #245) having proximal and distal portions and a prosthesis engaging element disposed on the distal portion; and an alignment guide surface (ref. #170/171) affixed to the spacer element and defining an alignment orifice (ref. #180), the alignment orifice being spaced apart from the prosthesis engaging element; and a spinal disc prosthesis (ref. #240) having an engaging element and a visual indicator element (surface of bone dowel ref. #240), the engaging element configured to releasably engage the prosthesis engaging element of the alignment verification device so that, upon engagement, the alignment orifice is spaced apart from the visual indicator element. The engagement of the alignment verification device with the prosthesis is adapted to permit a sighting element of an image obtaining device to be aligned with the alignment orifice and the visual indicator element so that an image obtaining device is aligned with the prosthesis in a known orientation. The spinal disc prosthesis incorporates an angle. The system further comprising an orientable image obtaining device including a sighting element for aiding in orienting the image obtaining device, the sighting device being aimable through the alignment orifice to the visual indicator element to provide a visual indication that the image obtaining device is oriented in a predetermined orientation with respect to the prosthesis. Zdeblick et al. further disclose a method for verifying the orientation of an image obtaining device with respect to an implanted prosthesis, comprising the steps of: providing an alignment verification device including a spacer element having proximal and distal portions and a prosthesis engaging element disposed on the distal portion;

and an alignment guide surface affixed to the spacer element and defining an alignment orifice, the alignment orifice being spaced apart from the prosthesis engaging element; engaging the alignment verification device to the implanted prosthesis, the prosthesis having an engaging element and a visual indicator element, the engaging element configured to releasably engage the prosthesis engaging element of the alignment verification device so that, upon engagement, the alignment orifice is spaced apart from the visual indicator element; orienting the image obtaining device so that a sighting element on the image obtaining device is aimed through the alignment orifice to the visual indicator element to provide a visual indication that a predetermined orientation between the image obtaining device and the prosthesis has been achieved.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zdeblick et al. (U.S. 6,595,995) in view of Pasquet et al. (U.S. 6,716,245).

Zdeblick et al. disclose the claimed invention except for the prosthesis engaging element being generally rectangularly shaped and the engaging element of the prosthesis being a slot configured to engage the prosthesis engaging element, and the prosthesis engaging element including a depth stop element, and the spacer element

including two elongate members with prosthesis engaging elements, and the prosthesis includes two engaging elements, each configured to engage one of the prosthesis engaging elements.

Pasquet et al. discloses a prosthesis engaging element being generally rectangularly shaped and the engaging element of the prosthesis being a slot configured to engage the prosthesis engaging element, and the prosthesis engaging element including a depth stop element, and the spacer element including two elongate members with prosthesis engaging elements, and the prosthesis includes two engaging elements, each configured to engage one of the prosthesis engaging elements.

(see FIG. 2) to provide a connection between an implant being inserted and the tool. Pasquet et al. discloses also discloses

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Zdeblick et al. with a prosthesis engaging element being generally rectangularly shaped and the engaging element of the prosthesis being a slot configured to engage the prosthesis engaging element, and the prosthesis engaging element including a depth stop element and , and the spacer element including two elongate members with prosthesis engaging elements, and the prosthesis includes two engaging elements, each configured to engage one of the prosthesis engaging elements in view of Pasquet et al. to provide a connection between an implant being inserted and the tool.

Claims 11 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zdeblick et al. (U.S. 6,595,995) in view of Lin (U.S. Patent No. 6,569,168).

Zdeblick et al. disclose the claimed invention except for a prosthesis including two engaging elements and two opposed bone facing surfaces each having a slot as the engaging element and the spacer element comprising two elongate members each having a prosthesis engaging element sized to engage a slot on the spinal disc prosthesis.

Lin discloses a prosthesis including two engaging elements and two opposed bone facing surfaces each having a slot as the engaging element and the spacer element comprising two elongate members each having a prosthesis engaging element sized to engage a slot on the spinal disc prosthesis to provide a connection between an implant being inserted and the tool.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Zdeblick et al. with a prosthesis including two engaging elements and two opposed bone facing surfaces each having a slot as the engaging element and the spacer element comprising two elongate members each having a prosthesis engaging element sized to engage a slot on the spinal disc prosthesis in view of Lin to provide a connection between an implant being inserted and the tool.

### ***Response to Arguments***

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/  
Examiner, Art Unit 3733  
/Eduardo C. Robert/  
Supervisory Patent Examiner, Art Unit 3733